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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,112	10/03/2003	Edward R. Kraft	ERK/001	2257
1473 7590 02/14/2008 ROPES & GRAY LLP PATENT DOCKETING 39/361 1211 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8704				
EXAMINER				
DESAI, ANAND U				
ART UNIT		PAPER NUMBER		
1656				
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02/14/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/679,112

**Applicant(s)**

KRAFT ET AL.

**Examiner**

ANAND U. DESAI

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-53 and 62-98 is/are pending in the application.
- 4a) Of the above claim(s) 28-30, 32-34, 62-79 and 81-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27, 31, 35, 39-44, 47, 48, 50, 80 and 97 is/are rejected.
- 7) ☒ Claim(s) 36-38, 45, 46, 49, 51-53 and 98 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on September 13, 2007. Claims 1-23 and 54-61 have been cancelled previously. Applicant's state in the remarks filed September 13, 2007 that the prior examiner has summarily withdrawn claims 67-79, however applicants traverse the withdrawal of these claims as they are not unelected. Applicants acknowledge the withdrawal of claims 28-30, 32-34, 62-66, and 81-96 as elected to a non-elected species. However in the response to the election of species, applicants elected a cytotoxic drug, therefore a species was elected and examined as a cytotoxic drug composition (see page 11 of December 15, 2006 Remarks document, and page 9, lines 25-26 of Remarks filed September 13, 2007). Claims 28-30, 32-34, 62-79, and 81-96 have been withdrawn previously and stand withdrawn as drawn to non-elected species. Applicants are entitled to consideration of claims to additional species which are written in dependent form or which otherwise include all the limitations of an allowed generic species as provided in accordance with 37 C.F.R. 1.141. New claims 97 and 98 have been added. Claims 24-27, 31, 35-53, 80, 97 and 98 are currently pending and are under examination.

#### **Withdrawal of Rejections**

2. The rejection of claim 31 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn based on applicants amendment to the claim to recite a cytotoxic drug.
3. The rejection of claims 24-27, 31, 39, and 40 under 35 U.S.C. 102(b) as being anticipated by Jiang et al. is withdrawn based on the amendment to claim 24 to recite transdermal delivery and applying a solution to a cellular surface on the skin.

4. The rejection of claims 24-27, 31, 35-53, and 80 under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. in view of Huang et al. and Kreindel et al. is withdrawn based on the amendment to claim 24 to recite transdermal delivery and applying a solution to a cellular surface on the skin.

### **Pending Objections and Rejections**

#### ***Specification***

5. The disclosure is objected to because of the following informalities:
6. There is a typographical error in amended paragraph [0070], the phrase “in the” is typed as int he.
7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 12 and page 15 for http:// links.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 42 is unclear, since amended claim 24 states the solution is applied to the skin.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 24-27, 31, 35, 39-44, 47, 48, 50, 80, and 97 are rejected under 35 U.S.C. 102(a) as being anticipated by Dijkstra et al. (Journal of the European Academy of Dermatology and Venereology 15: 550-554 Nov. (2001)).

Dijkstra et al. disclose the photodynamic therapy with violent light and topical  $\delta$ -aminolaevulinic acid ( $\delta$ -ALA) in the treatment of actinic keratosis, Bowen's disease and basal cell carcinoma.

20%  $\delta$ -ALA was applied topically, photoirradiation was performed with an incoherent light source (Phillips HPM-10, 400 W) emitting predominantly violet light (400-450 nm). The lesions received 10-20 J/cm<sup>2</sup> during an exposure time of 30 minutes. The  $\delta$ -ALA was mixed with Instillagel® (see page 550, Abstract, Methods section, and page 551, Photosensitizer section).

Instillagel® is a sterile gel containing a local anaesthetic and antiseptic presented in a sterile package. Active ingredients are (in each 100 grams):

Lignocaine Hydrochloride (Local anaesthetic) 2.000g

Chlorhexidine Gluconate Solution (Antiseptic) 0.250g

Methyl Hydroxybenzoate (E218) (Antiseptic) 0.060g

Popyl Hydroxybenzoate (E216) (Antiseptic) 0.025g

in a gel made with Hydroxyethylcellulose, Propylene Glycol and Purified Water. (see <http://www.clinimed.co.uk/cl/products/Intl/instillagel/>).

### ***Claim Objections***

13. Claims 36-38, 45, 46, 49, 51, 52, 53, 97, and 98 are objected to because of the following informalities:
14. Claims 36-38, 45, 46, 49, 52, 53, and 98 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
15. In claim 51, the abbreviation cps should be spelled out as cycles per second at its first occurrence in the claims.
16. Claim 97 is objected to for comprising non-elected subject matter.  
Appropriate correction is required.

### ***Conclusion***

17. No claims are allowed.
18. This application contains claims 28-30, 32-34, 62-79, and 81-96 drawn to an invention nonelected with traverse in the reply filed on September 13, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 11, 2008

/Anand U Desai, Ph.D./  
Patent Examiner, Art Unit 1656

/Robert B Mondesi/  
Primary Examiner, Art Unit 1652